

Docket No. 0327-0815-0

IN RE APPLICATION OF: Keiko HASEBE, et al.

SERIAL NO: 09/468,777

FILED: DECEMBER 21, 1999

CPA Filed: November 20, 2001

FOR: AMPHIPATIC LIPID DISPERSION

ASSISTANT COMMISSIONER FOR PATENTS  
WASHINGTON, D.C. 20231



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RESPONSE UNDER 37 CFR 1.116  
EXPEDITED PROCEDURE EXAMINING  
GROUP 1617

TECH CENTER 1000  
AUG 16 2002

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SIR:

Transmitted herewith is a **RESPONSE AND REQUEST FOR RECONSIDERATION** Under 37 C.F.R. 1.116 in the above-identified application.

- ☒ No additional fee is required
- ☐ Small entity status of this application under 37 C.F.R. §1.9 and §1.27 is claimed.
- ☒ Additional documents filed herewith: **(4) Attachments**

The Fee has been calculated as shown below:

CLAIMS	CLAIMS REMAINING		HIGHEST NUMBER PREVIOUSLY PAID	NO. EXTRA CLAIMS	RATE	CALCULATIONS
TOTAL	17	MINUS	20	0	× \$18 =	\$0.00
INDEPENDENT	2	MINUS	3	0	× \$84 =	\$0.00
		<input type="checkbox"/> MULTIPLE DEPENDENT CLAIMS			+ \$280 =	\$0.00
		TOTAL OF ABOVE CALCULATIONS				\$0.00
		<input type="checkbox"/> Reduction by 50% for filing by Small Entity				\$0.00
		<input type="checkbox"/> Recordation of Assignment			+ \$40 =	\$0.00
		TOTAL				\$0.00

- ☐ A check in the amount of **\$-0-** is attached.
- ☒ Please charge any additional Fees for the papers being filed herewith and for which no check is enclosed herewith, or credit any overpayment to deposit Account No. 15-0030. A duplicate copy of this sheet is enclosed.
- ☒ If these papers are not considered timely filed by the Patent and Trademark Office, then a petition is hereby made under 37 C.F.R. §1.136, and any additional fees required under 37 C.F.R. §1.136 for any necessary extension of time may be charged to Deposit Account No. 15-0030. A duplicate copy of this sheet is enclosed.

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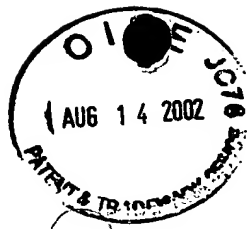
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0327-0815-0



IN THE UNITED STATES PATENT & TRADEMARK OFFICE

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8-28-02

IN RE APPLICATION OF :

Keiko HASEBE, et al.

: EXAMINER: WELLS

SERIAL NO.: 09/468,777

: GROUP ART UNIT: 1617

FILED: DECEMBER 21, 1999 :

CPA Filed: November 20, 2001

FOR: AMPHIPATIC LIPID  
DISPERSION :

RESPONSE UNDER 37 CFR 1.118-  
EXPEDITED PROCEDURE EXAMINING  
GROUP 1617

RESPONSE AND REQUEST FOR RECONSIDERATION

ASSISTANT COMMISSIONER FOR PATENTS  
WASHINGTON, D.C. 20231

SIR:

In response to the outstanding Official Action of May 14, 2002, reconsideration of the above-identified application is respectfully requested in view of the following remarks:

REQUEST FOR RECONSIDERATION

Claims 11-21 remain active in this application.

The present invention is directed to a dispersion of an amphipathic lipid as a **solid** particulate **dispersed** in a surfactant and aqueous medium.

The rejections of Claims 11-19 under 35 U.S.C. §103(a) over Nakamura et al. EP 487,958, Dubief et al. U.S. 5,679,357 and Pillai et al. U.S. 5,476,661 each in view of Vanlerberghe et al. U.S. 5,985,255 or Young U.S. 4,152,272 are respectfully traversed.

None of the cite references discloses or suggests a dispersion of amphipathic lipid as a **solid** particulate of the claimed particle size **dispersed** in surfactant and aqueous medium.

Nakamura et al. describe a composition in which the amphipathic lipid is present as an emulsion (containing a **liquid** dispersoid). Dubief et al also describe a composition as an emulsion.

In contrast, the present invention is directed to a dispersion of amphipathic lipid as a **solid particulate**, the solid particulate being **dispersed in** surfactant and aqueous medium.

Applicants respectfully submit that the emulsions of the two cited references fail to disclose or suggest a **solid particulate being dispersed** in a surfactant and aqueous medium. An emulsion is directed a colloid in which a **liquid** is dispersed through a **liquid**. As evidence of the technical understanding of the term emulsion, applicants enclose herewith a passage from Sienko and Plane *Chemical Principles and Properties* second edition (1974). Applicants further note that the reference identifies a colloid in which a **solid** is dispersed through a **liquid**, as a **sol**.

Additional evidence of the differences between an emulsion and a suspension is found in the attached passages from *Ullmann's Encyclopedia of Industrial Chemistry* fifth completely revised edition (VCH Verlagsgesellschaft mbH 1987) and *Dispersions Characterization, Testing, and Measurement* by Erik Kissa (Marcel Dekker 1999). In both cases emulsions and suspensions are characterized as liquid/liquid and liquid/solid systems respectively.

Applicants appreciate the examiner's attempt to clarify the meanings of the terms "emulsion" and "dispersion" by providing dictionary definitions. However, while the dictionary definitions provides evidence that an emulsion is a type of a dispersion (a liquid dispersed in an immiscible liquid), the dictionary definitions do not suggest that an emulsion is a type of **solid** dispersion.

Accordingly, the **claim limitation of solid** particulate is a claim limitation which is nowhere disclosed or suggested in the cited primary references as the references are directed to a dispersion of a **liquid**. In view of the deficiencies of the primary references the claimed invention simply can not be suggested by the references.

Pillai et al. does not disclose any solid particles or particle size whatsoever.

Since the reference fails to disclose or suggest solid particles of amphipathic lipid in any context, the reference can not suggest a dispersion in which the amphipathic lipid is a **solid particulate** and **dispersed** in a surfactant and aqueous medium. While the examiner has cited to the decision *In re Rose* as basis for the obviousness of selection of particle size, in the present case, the examiner presupposes that the reference of Pillai et al describes a particle of lipid of any size. In fact, the reference fails to describe a composition in which an amphipathic lipid is a solid in a surfactant and an aqueous medium. As the reference fails to describe a composition in which the amphipathic lipid is in solid form, the reference can not suggest an amphipathic lipid as a solid particulate which is dispersed in surfactant and aqueous medium. Accordingly the claim limitation of the amphipathic lipid being a **solid particulate** is a claim limitation which is not found in the cited reference and accordingly the claimed invention can not be found to be obvious therefrom.

Since the cited reference nowhere discloses or suggests the lipid component **dispersed as a solid particulate**, the present invention is clearly not obvious from these references and accordingly withdrawal of the rejections under 35 U.S.C. §103(a) is respectfully requested. Moreover, since none of the primary references disclose or suggest the amphipathic lipid in the form of a solid particulate, there can be no suggestion of the claimed invention by the secondary references. The claim element of an amphipathic lipid in the form of a **solid particulate dispersed in surfactant and aqueous medium** is a claim

limitation which is nowhere disclosed or suggested in the cited references and accordingly the claimed invention is not obvious over the cited art.

In addition, Applicants have previously provided evidence of the improved reduction of surfactant retention on the skin on November 20, 2001, *via* the declaration of Mr. Keiko Hasebe a named inventor of the above-identified application. The data measured the surfactant retention on the skin, for a cleansing system which contains an amphipathic lipid dispersion as claimed, as compared with a cleansing system containing a solid lipid dispersion of a substance outside the claims (e.g. ethyleneglycol distearate) but of similar particle size or no dispersion at all. For the examiner's convenience a portion of the data is reproduced below:

The results are shown in Table 3.

Table 3

	Amount of lauryl ether acetate salt in <i>stratum corneum</i> ( $\mu\text{g}/\text{cm}^2$ -skin)		
	Systemic cleansing agent		
	A (Blank)	B (Present product)	C (Comparative product)
Average adsorption amount $\pm$ SD	$3.0 \pm 0.9$	$1.3 \pm 0.5$	$3.2 \pm 0.5$

From the results in Table 3, it is apparent that the present product significantly reduces adsorption of the surfactant on the skin whereas comparative product C without any amphipathic lipid does not exhibit such effect although it contains a solid lipid having a particle size similar to that of the amphipathic lipid contained in the present product. When a detergent composition containing a substance outside the scope of the present invention but having a particle size similar to that of the present invention, a detergent base material or surfactant residue was observed on the skin after rinsing and accordingly the effect of

controlling residual detergent base is not present. Such a result is nowhere disclosed or suggested in the cited prior art of record.

The rejections of Claim 15 under 35 U.S.C. §112, second paragraph, is respectfully traversed.

Applicants respectfully submit that the metes and bounds of the term “psuedoceramide” is clear to those of ordinary skill in the art, as evidence by the use of this term in claims of U.S. patents. Attached is a print out of a patent term search from the U.S.P.T.O. data base of patents issued from 1996 to 2002 in which the term “pseudoceramide” appears in the claims. Five patents were identified. Moreover, the very reference cited by the examiner of Pillai et al. uses the term “pseudoceramide” throughout the specification (e.g. column 4, line 31) As such the term is evidenced to be well known to those of ordinary skill in the art, such that the metes and bounds of the claimed invention is clear to those of ordinary skill in the art. Withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Applicants submit that this application is now in condition for allowance and early notification of such action is earnestly solicited.

Respectfully submitted,

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